

Claims:

1. Hydrated N-[3-[[2-(3,4-dimethoxyphenyl)ethyl]amino]propyl]-4-nitro benzamide hydrochloride characterised in that it:
 - 5 (i) comprises water in the range of from 1.7 to 2.4 molar equivalents; and/or
 - (ii) has a melting point above 145°C and/or
 - (iii) provides an infra red spectrum containing peaks at 3510, 3342, 3076, 1665, 1598, 1343, 1330, 1216 and 801 cm⁻¹; and/or
 - 10 (iv) provides a solid state nuclear magnetic resonance spectrum containing chemical shifts substantially as represented in Table I; and/or
 - (v) provides an X-ray powder refraction (XRPD) pattern substantially as represented in Table II.
2. A compound according to claim 1, which comprises from 1.8 to 2.3 or 1.9 to 2.1
15 molar equivalents of water.
3. A compound according to claim 1 or claim 2, which comprises 2.0 molar equivalents.
- 20 4. A compound according to any one of claims 1 to 3, which has a melting point in the range of from 150°C to 154°C.
5. A compound according to any one of claims 1 to 4, which has a melting point of 150°C, 151°C, 152°C, 153°C or 154°C.
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6. A compound according to any one of claims 1 to 5, which provides an infra red spectrum containing peaks at 3510, 3342, 3307, 3076, 1665, 1632, 1598, 1548, 1520, 1343, 1330, 1310, 1267, 1240, 1216, 1162, 1147, 1119, 1105, 1048, 1036, 1025, 981, 921, 891, 873, 854, 801, 767, 720, 626, 573, 553 and 500 cm⁻¹.
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7. A compound according to any one of claims 1 to 6, which provides an infra red spectrum substantially as illustrated in Figure (I).
8. A process for preparing hydrated N-[3-[[2-(3,4-
35 dimethoxyphenyl)ethyl]amino]propyl]-4-nitrobenzamide hydrochloride according to claim 1, characterised in that N-[3-[[2-(3,4-dimethoxyphenyl)ethyl]amino]propyl]-4-

nitrobenzamide hydrochloride, is hydrated in the presence of the required amount of water.

9. A process according to claim 8, wherein the Hydrochloride is crystallised or
5 recrystallised from water or an aqueous solvent.
10. A pharmaceutical composition comprising Compound (I) according to claim 1, or
a pharmaceutically acceptable salt thereof and/or a pharmaceutically acceptable solvate
thereof, and a pharmaceutically acceptable carrier.
- 10 11. Compound (I), according to claim 1, or a pharmaceutically acceptable salt thereof
and/or a pharmaceutically acceptable solvate thereof, for use as an active therapeutic
substance.
- 15 12. Compound (I), according to claim 1, or a pharmaceutically acceptable salt thereof
and/or a pharmaceutically acceptable solvate thereof, for use in the treatment of and/or
prophylaxis of arrhythmia and ischaemic rhythm disorders.
- 20 13. The use of Compound (I), according to claim 1, or a pharmaceutically acceptable
salt thereof and/or a pharmaceutically acceptable solvate thereof, for the manufacture of a
medicament for the treatment of arrhythmia and ischaemic rhythm disorders.
- 25 14. A method for the treatment and/or prophylaxis of arrhythmia and ischaemic
rhythm disorders in a human or non-human mammal which comprises administering an
effective, non-toxic, amount of Compound (I), or a pharmaceutically acceptable salt
thereof and/or a pharmaceutically acceptable solvate thereof to a human or non-human
mammal in need thereof.